

Resources: www.lifesciencestartup.com, the Arizona Department of Commerce (Commerce) and Science Foundation Arizona (SFA), & SCORE

Additional Resources

- ◆ Two additional tools accompany this *Quick Reference Guide*: a more detailed *Resource Guide*, and a visual *Presentation* highlighting the process explained in this Guide.
- ◆ The National Institutes of Health Grants Process Overview
<http://grants.nih.gov>
- ◆ The Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Program
<http://www.sbir.gov/>
- ◆ SBA and information on Starting a Business
www.sba.gov
- ◆ SCORE Association
www.score.org
- ◆ Association of Small Business Development Centers
www.asbdc-us.org
- ◆ StartupNation is a free service founded by entrepreneurs for entrepreneurs.
<http://www.startupnation.com>
- ◆ National Venture Capital Association
<http://www.nvca.org>



Johns Hopkins Carey Business School

DISCLAIMER: This document was developed in response to an academic assignment that can enable researchers to understand and apply business processes and principles to improving their success in receiving grant funds from NIDDK. This Guide is designed for scientific researchers like you, who may have conceived an invention that you believe has commercial potential. The goal of this project is to provide an easy-to-comprehend and informative overview of the "concept-to-commercialization" process. Please note that the policies, procedures and legal issues of commercializing inventions differ among universities, private sector and government organizations. Therefore, you should consult your respective intellectual property and technology transfer offices for compliance information and specific procedures. While this Guide is an introduction to the scientific commercialization process, it is not all-inclusive. Additional resources are provided in the appendix for those seeking a comprehensive treatment of this topic.



Scientific Commercialization Quick Reference Guide



See the National Institute of Diabetes and Digestive and Kidney Diseases Small Business website for more information
<http://www2.nidDK.nih.gov/Funding/SmallBusiness/>

Technology Commercialization Process

This document provides a high level overview of the Technology Commercialization Process, which presents the process and procedures for scientists and researchers to take a concept, whether an idea, drug or process, from its initial development stages to commercialization.



Diagram of the Technology Commercialization Process

Come up with the Idea and Complete the Initial Steps

- ◆ Identify and develop smart, fundable opportunities
- ◆ Understand the importance of The Office of Technology Transfer (OTT), who has the manpower and tools to analyze and assist faculty inventors to commercialize
- ◆ The Patent Application processes Important legal issues to be aware of and follow



Develop your Business Plan

Our document will help you understand the purpose and importance of the Business Plan as a strategic road map. It is a key component to securing funding.

The Business Plan

- ◆ Determines and supports strategy
- ◆ Evaluates the market and competition
- ◆ Identifies strengths and weaknesses
- ◆ Analyzes your business' current financial condition and potential profits

Perform Market Research to Ensure Success

Understanding your market is a critical piece to explore at the beginning of your path as a researcher who is developing a product to commercialize. Our document will guide you in being able to:

- ◆ Review and identify
- ◆ Answer the question: What is PEST?
- ◆ Understand the 3 Cs (the customer, competition and core competence) and micro environment factors
- ◆ Focus on decision gates: What, When, Why, How, 'If, Then'

Finance and Accounting Makes the Concept a Reality

Access to finance is a key factor in commercialization. Not every source of funding have the same purpose nor accessibility. The Potential Funding Sources chart found on the back of the brochure, outlines the various funding sources at various developmental stages.

Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs

The largest amount of money to support biomedical research is available through federal programs, primarily the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs, associated with the National Institutes of Health and the Department of Defense. NIH has one of the largest SBIR/STTR programs focusing on biotechnology and biomedical products.



Risk Management is a Must!

We understand there is a lot at stake regarding time, money, and resources. Therefore, we provide the tools to help you assess and handle your risks by:

- ◆ Defining Risks and their importance
- ◆ Planning for risk management and continuous monitoring throughout the lifecycle
- ◆ Documenting and evaluating against priority and impact is important
- ◆ Mitigate before it becomes an issue



Are you ready to start a clinical trial?

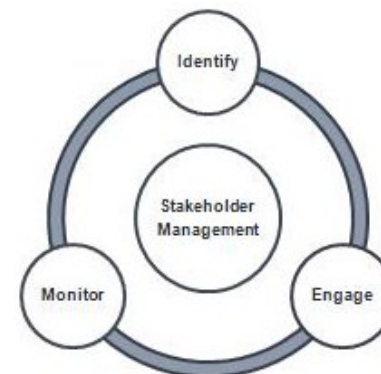
We will navigate you through the detailed process of this step by:

- ◆ Giving an overview of the FDA approval process for your Investigational New Drug (IND) or Investigational New Device (IDE)
- ◆ Provide a multitude of resources so that you may submit your application with the most success.

Managing Relationships

Clearly, your journey to commercialize cannot be done alone. Our document will aid to:

- ◆ Identify Stakeholders, their roles and level of influence
- ◆ Discuss how to engage through ongoing communications
- ◆ Monitor effectiveness and update plan as required



Your Quick Checklist to Getting Started

- ☐ Define your business concept or idea
- ☐ Do your research (market, industry, competition, etc.)
- ☐ Engage your institute's Tech Transfer Office
- ☐ Determine your start-up costs
- ☐ Determine business structure
- ☐ Develop a Business plan
- ☐ Create and register your business structure
- ☐ Investigate licensing requirements
- ☐ Determine financing options
- ☐ START your business